

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF CALIFORNIA

SHERRILL MORTON and WILLIAM	)	
MORTON,	)	NO. CIV S-03-2602 GEB GGH
	)	
Plaintiffs,	)	
	)	
v.	)	ORDER
	)	
CENTERPULSE ORTHOPEDICS, INC.,	)	
	)	
Defendant.	)	
_____	)	

Defendant Centerpulse Orthopedics Inc. moves for summary judgment on all of Plaintiffs' claims, contending that the claims are preempted by 21 U.S.C. § 360k(a) (the Medical Devices and Cosmetics Act), and that the claims are legally untenable under state law and are not factually supported. Plaintiffs oppose the motion.

Background

In January 1999, after it was determined that Plaintiff Sherrill Morton needed a knee replacement surgery, Ms. Morton's doctor, Dr. Ronald Carn, implanted a Natural Knee System which was manufactured by Defendant in Ms. Morton's right knee. In July 2002, Ms. Morton experienced an acute pain in her right knee, and in August 2002, Dr. Carn replaced three of the components of her Natural Knee

1 System. Upon examination, Dr. Carn determined that the polyethylene  
2 portion of the patella component of the system ("Patella Component")  
3 had broken. Plaintiffs then initiated this action for strict product  
4 liability based on manufacturing and design defects; general  
5 negligence based on negligent design, manufacture, and provision of  
6 warnings; breach of warranty; and loss of consortium. (Pls.'  
7 Complaint at 4-6; Pls.' Opp'n to Mot. for Summ. J. at 4.)

8         The Medical Device Amendments ("MDA") to the Food, Drug and  
9 Cosmetic Act created three classes of medical devices based on the  
10 degree of regulation needed to assure the safety and effectiveness of  
11 the medical device. 21 U.S.C. § 360c(a)(1). Class I devices present  
12 no unreasonable risk of illness or injury and are subject only to  
13 minimal regulation by "general controls." Id. § 360c(a)(1)(A). Class  
14 II devices are potentially more harmful and are subject to certain  
15 "special controls." Id. § 360c(a)(1)(B). Class III devices either  
16 "present[] a potential unreasonable risk of illness or injury" or are  
17 "purported or represented to be for a use in supporting or sustaining  
18 human life or for a use which is of substantial importance in  
19 preventing impairment of human health." Id. § 360c(a)(1)(C). In  
20 order to introduce a Class III device to the market, manufacturers of  
21 Class III devices must receive premarket approval ("PMA") from the  
22 United States Food and Drug Administration ("FDA") by providing the  
23 FDA with a "reasonable assurance" that the device is both safe and  
24 effective. Id. § 360e(d)(2). "Manufacturers must submit detailed  
25 information regarding the safety and efficacy of their devices, which  
26 the FDA then reviews, spending an average of 1,200 hours on each  
27 submission." Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996).



liability assert standards which are inconsistent with the FDA requirements. (Def.'s Mot. for Summ. J. at 9-24.)

The MDA has a preemption provision which provides:

[N]o State . . . may establish or continue in effect with respect to a device intended for human use any requirement- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). There is a split in authority regarding whether this provision preempts state tort claims in which damages are sought for alleged defective "medical devices that have received PMA approval." Gilleon v. Medtronic USA, Inc., 2002 WL 31300694, at \*4 (N.D. Cal. Aug. 28, 2002). "The majority of circuits to have addressed the issue have held that the PMA process results in preemption, at least of common law claims contending that the approved product design is defective or unreasonably dangerous or that allege that the approved labeling or warnings are inadequate." Id. (citing Brooks v. Howmedica, Inc., 273 F.3d 785, 799 (8th Cir. 2001); Martin v. Medtronic, 254 F.3d 573, 584 (5th Cir. 2001); Kemp v. Medtronic, 231 F.3d 216, 226-28 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902, 911 (7th Cir. 1997); see also Steele v. Collagen Corp., 54 Cal. App. 4th 1476, 1487 (1997)). "The Eleventh Circuit, however, reached a contrary conclusion, in Goodlin v. Medtronic, 167 F.3d 1367 (11th Cir. 1999), finding that the common law tort claims are not preempted by the MDA." Gilleon, at \*4.

"[T]he cases on both sides of the split are well-reasoned and defensible." Id. "The substantive split among the circuits reveals a methodological difference: the majority focuses on the rigor

1 of the PMA process and often restrictive post-approval conditions,  
2 whereas the minority focus on congressional intent as expressed in the  
3 statute." Webster v. Pacesetter, Inc., 171 F. Supp. 2d 1, 9 (D.D.C.  
4 2001). "Thus, courts that look to the rigors of the PMA approval  
5 process, the FDA's involvement in approving the design of the device,  
6 the warnings to be given for the device, and the contents of labeling,  
7 conclude that the PMA approval constitutes device specific federal  
8 requirements which would be undermined if state common law claims  
9 could be brought and which would impose different or additional  
10 requirements." Gilleon, 2002 WL 31300694, at \*4.

11 Although the Ninth Circuit has not decided whether the MDA  
12 preempts state products liability lawsuits over medical devices that  
13 have received PMA approval, the district court in Gilleon, after  
14 considering Ninth Circuit authority on whether "state common law  
15 claims can amount to 'requirements' which may be preempted under the  
16 MDA," predicted that "the Ninth Circuit would agree with the majority  
17 view and hold that PMA approval of a Class III device gives rise to  
18 preemption of state law claims." Gilleon, 2002 WL 31300694, at \*4, 5.

19 The rationale of Gilleon is persuasive and will be followed.  
20 Therefore, in accordance with the majority view, the PMA approval of  
21 the Natural Knee System Patella Component "results in preemption of  
22 state common law claims, to the extent those claims seek to impose  
23 requirements that are different or in addition to those required by  
24 federal law." Id. But, Plaintiffs also allege that "there is a  
25 genuine issue of material fact related to whether or not defendant  
26 followed federal regulations and its PMA related [to] the design,  
27 manufacturing, and labeling of the product which is the subject of  
28 this lawsuit." (Pls.' Opp'n to Mot. for Summ. J. at 12.)

1 Ms. Morton alleges Defendant defectively manufactured the  
2 Patella Component. However, no genuine issue of material fact has  
3 been raised as to whether Defendant complied with all FDA requirements  
4 related to the manufacture of the Patella Component. (SUF ¶¶ 3,4.)  
5 Therefore, summary judgment is granted for Defendant on Ms. Morton's  
6 defective manufacturing claims.

7 Ms. Morton also alleges a product liability claim based on  
8 defective design of the Patella Component. The FDA granted premarket  
9 approval of the design of the device, but Defendant has not set forth  
10 specific facts in its Statement of Undisputed Facts indicating that it  
11 complied with the design which was approved by the FDA. However, in  
12 California, "the entire category of medical implants available only by  
13 resort to the services of a physician are immune from design defect  
14 strict liability." Artiglio v. Superior Court, 22 Cal. App. 4th 1388,  
15 1396-97 (1994). Since no genuine issue of material fact exists as to  
16 whether the Patella Component is an implanted prescription medical  
17 device that may only be sold to physicians, Defendant's motion for  
18 summary judgment on Ms. Morton's strict liability claim for defective  
19 design is granted.

20 Ms. Morton also alleges Defendant failed to adequately warn  
21 her or her physician about the potential adverse effects of the  
22 Patella Component. However, Defendant included with the device a  
23 package insert titled "Important Information for the Operating  
24 Surgeon," which was specifically approved by the FDA, and which warned  
25 that "the potential adverse effects of the Intermedics Natural Knee  
26 System are similar to those occurring with any total knee replacement.  
27 These effects are often attributable to factors listed under Warnings  
28 and Precautions and commonly include: (1) Changing position of the

1 prosthesis with or without loosening of cement or clinical symptoms.  
2 Bending and/or fracture of the components . . . ." (SUF ¶¶ 8,9.)  
3 Plaintiffs dispute paragraph 8, citing to a portion of Dr. Ronald M.  
4 Carn's Declaration, but the cited portion says nothing about whether a  
5 warning was given. Plaintiffs also dispute paragraph 9, citing to  
6 evidence that does not controvert Defendant's statement that this  
7 information was given to Ms. Morton's physician. Therefore, summary  
8 judgment is granted for Defendant on Ms. Morton's claims for failure  
9 to adequately warn.

10 Ms. Morton also claims Defendant breached both express and  
11 implied warranties. However, Ms. Morton admitted in her deposition  
12 testimony that "neither Dr. Carn nor anybody else made any  
13 representations or assurances about the outcome of the operation."  
14 (Deposition of Sherrill Morton at 37, lines 8-11.) (See also SUF ¶  
15 11.) Plaintiffs dispute paragraph 11, citing to evidence which does  
16 not controvert Defendant's factual showing that it made no warranties  
17 to her.<sup>2</sup> Accordingly, Defendant's summary judgment motion on Ms.  
18 Morton's claim for breach of an express warranty is granted.

19 Defendant also asserts it did not breach an implied warranty  
20 to Ms. Morton because Ms. Morton was never in privity of contract with  
21 Defendant. (SUF ¶ 12.) See Fieldstone Co. v. Briggs Plumbing  
22 Products, Inc., 54 Cal. App. 4th 357, 362 (1997) (citations omitted)  
23 (stating that "Vertical privity is a prerequisite in California for  
24 recovery on a theory of breach of the implied warranties of fitness  
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26 <sup>2</sup> Plaintiffs cite to the declaration of Larry Beeman at Page  
27 2, lines 10 and 11; the deposition of Sherrill Morton at page 30, line  
28 23 to page 31, line 4; and the deposition of William Morton at page  
13, line 24 to page 14, line 15. However, none of this evidence  
indicates that Defendant made any warranties to Ms. Morton.

1 and merchantability." ). Plaintiffs dispute paragraph 12, citing to  
2 evidence which does not controvert Defendant's factual showing that it  
3 was never in privity with Ms. Morton.<sup>3</sup> Therefore, Defendant is  
4 granted summary judgment on Ms. Morton's claim for breach of an  
5 implied warranty.

6 Defendant also seeks summary judgment on Ms. Morton's claim  
7 that Defendant was negligent. However, Defendant has not set forth  
8 specific facts in its Statement of Undisputed Facts that it complied  
9 with the FDA-approved design. Since Defendant has not met its burden  
10 of establishing that there is no genuine issue of material fact as to  
11 this claim, Defendant's motion for summary judgment on Ms. Morton's  
12 negligence claim is denied.

13 Finally, Plaintiff William Morton alleges loss of  
14 consortium. Since this claim is derivative, and Defendant has not  
15 established that there is no genuine issue of material fact as to  
16 Defendant's negligence, Defendant's motion for summary judgment on Mr.  
17 Morton's loss of consortium claim based on Defendant's negligence is  
18 denied.

19 IT IS SO ORDERED.

20 Dated: May 10, 2005

21 /s/ Garland E. Burrell, Jr.  
22 GARLAND E. BURRELL, JR.  
23 United States District Judge  
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26 <sup>3</sup> Plaintiffs cite to the declaration of Larry Beeman at Page  
27 7, lines 4 to 6, and page 2, lines 10 and 11; the deposition of  
28 Sherrill Morton at page 112, lines 4 to 8, and lines 16 to 25; and the  
declaration of Dr. Ronald M. Carn. However, none of this evidence  
indicates that Ms. Morton was ever in privity with Defendant.